K100602

5. 510(k) Summary

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(as required by 21 CFR 807.92)

AUG 17 2011

Submitter: **Nova Biomedical Corporation**
200 Prospect Street
Waltham, MA 02454 U.S.A.

Correspondent: Paul W. MacDonald
Chief Quality Assurance and Regulatory Affairs Officer

Phone: 781-894-0800 ex 211; Fax: 781-891-4806
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Device Name:
Nova StatStrip Lactate Hospital Meter System

Common Name:
Blood Lactate Test System

Classification:
Division of Clinical Laboratory Devices
Clinical Chemistry
Lactate dehydrogenase test system.
Class II per 21 CFR 862.1440

Product Codes:
CFJ, KHP

Predicate Devices:
KDK Corporation Lactate Pro System, K980908 (handheld meter)
Nova Biomedical StatProfile pHOx Plus L K023567, K012058 (analyzer)

Description of the Device:

The Nova StatStrip Lactate Hospital Meter System consists of:

1. Nova StatStrip Lactate Hospital Meter
2. Nova StatStrip Lactate Test Strips
3. Nova StatStrip Lactate Control Solutions (Levels 1 and 2)
4. Nova StatStrip Lactate Linearity Solutions (Levels 1,2,3 and 4)
5. Meter Docking Station

Intended Use/Indications for Use:

Meter:
The Nova StatStrip Lactate Hospital Meter System is intended for in vitro diagnostic use by health care professionals for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens. It is not for use on capillary blood specimens. It is intended to provide plasma equivalent results to laboratory methods. The Nova StatStrip Lactate Hospital Meter System is indicated for use in a clinical setting by healthcare professionals as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis.

Test Strips:
Nova StatStrip Lactate Test Strips are intended for use only with Nova StatStrip Lactate Hospital Meter for quantitative determination of lactate in fresh venous and arterial whole blood specimens. It is not for use on capillary blood specimens. The performance characteristics of the device for lactate measurements on capillary specimens have not been established. Nova StatStrip Lactate Test Strips are for testing outside the body (in vitro diagnostic use only).

Control Solutions:
Nova StatStrip Lactate Control Solutions are intended for use with the Nova StatStrip Family of Meters and Nova StatStrip Lactate Test Strips as a quality control check to verify the accuracy of blood lactate test results. There are 2 levels of controls, (Level 1 and Level 2).

Nova StatStrip Lactate Linearity Kit solutions are used to check the linearity of the Nova StatStrip Family of Meters. There are 4 levels of lactate linearity solutions: Level 1, Level 2, Level 3, and Level 4.

Summary of Technological Characteristics:

The Nova StatStrip Lactate Hospital Meter System has similar fundamental scientific technology and a similar intended use as the currently marketed Lactate Pro System (K980908).

Both the Lactate Pro and the proposed Nova StatStrip Lactate Hospital Meter System are hand held devices with similar intended use to quantitatively measure the lactate levels in whole blood. The principle of operation is the same for the proposed and predicate device. Each utilizes a test strip that is inserted into a meter for results within 13 seconds.

Comparison to Predicate Devices:

The proposed Nova StatStrip Lactate Hospital Meter System uses the same fundamental scientific technology, similar specifications, and has a similar intended use as the predicate Lactate Pro System (K980908). In addition, the proposed Nova StatStrip Lactate Hospital Meter System can produce equivalent results to the previously cleared Nova Biomedical StatProfile pHOx Plus L (K023567, K012058), which is a tabletop multianalyte chemistry analyzer.

Performance Studies:

Laboratory and clinical testing was performed on the proposed Nova StatStrip Lactate Hospital Meter System. The studies demonstrated that the blood lactate results were substantially equivalent to the current methods for blood lactate measurements.

Conclusion:

Results of laboratory and clinical testing demonstrate that the performance of the Nova StatStrip Lactate Hospital Meter System has the same intended uses, with similar technological characteristics and can produce results that are substantially equivalent to results obtained on the predicate devices. The system performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Nova Biomedical Corporation
c/o Mr. Paul W. MacDonald
Chief Quality Assurance/Regulatory Affairs Officer
200 Prospect Street
Waltham, MA 02454-9141

AUG 17 2011

Re: k100602
Trade/Device Name: Nova StatStrip Lactate Hospital Meter System.
Regulation Number: 21 CFR 862.1450
Regulation Name: Lactic acid test system.
Regulatory Class: Class I, meets limitations of exemptions per 21 CFR 862.9(c)(9)
Product Code: KHP, JJX
Dated: August 15, 2011
Received: August 16, 2011

Dear Mr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K100602

Device Name: **Nova StatStrip Lactate Hospital Meter System**

Indications for Use:

Meter:
The Nova StatStrip Lactate Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals for multiple patient use in a professional healthcare setting for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis. It is not for use on capillary blood specimens. It is intended to provide plasma equivalent results to laboratory methods.

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Updated February 3, 2005)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K100602